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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,408

06/27/2003

Brian R. Will

WILB01

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7590

07/14/2006

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,408	WILL, BRIAN R.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 13, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant argues that the person having ordinary skill in the art would not be motivated to produce a device such as claimed given L'Esperance (EP '127) or Hellencamp. L'Esperance (EP '127) is theorized to be inapplicable apparently because the "air-permeable and wall of L'Esperance is easily clogged by mucous". However applicant gives no particular evidence to bolster this assertion. The examiner offers, by way of evidentiary showing to the contrary, that L'Esperance, Jr. (US '148) discloses such a structure (see Figure 2 therein), while L'Esperance, Jr. (US '172) incorporates the aforementioned L'Esperance, Jr. (US '148) by reference and specifically claims (see claims 12, 13, and 19 therein) such an eye-fixation means. As these issued US Patents enjoy a presumption of validity, the claimed "annular eye retainer" that is "applied to the cornea for pre operative eye fixation" must, in fact, fix the eye, which requires that the air permeable membrane be designed such that it is not clogged by mucous. Thus theories put forth by applicant's representative, devoid of factual evidence or proof of any kind, are insufficient to overcome the evidentiary showing put forth by the examiner, and these arguments are not convincing. As to the assertion that the pores of the wall of the L'Esperance (EP '127) device would absorb fluid from the eye and thereby cause damage thereto, again applicant has proffered little other than opinion and conjecture. The examiner again points to the claims of L'Esperance, Jr. (US '172), claim 1 reciting "Changing the optical properties of an eye by operating **solely upon the optically used area of the anterior surface of the cornea**" (emphasis added). Clearly, if a portion of the conjunctiva is removed by the agency theorized by applicant, this would constitute operating on a portion of the eye which was other than the optically used portion of the cornea. Further, it is not clear how a removal of tissue would

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produce the alleged “bulging” referred to in applicant’s remarks. Thus these arguments are also not convincing.

Similarly, with regard to Hellencamp, applicant theorizes a problem with the reference, but does not associate it with any particular structure of the device. For example, while applicant’s arguments may be applicable to the embodiment of Figures 3A and 3B of Hellencamp, it is clear that the circular, non-peripheral ports of Figure 3C would limit the applied vacuum to the ports themselves and would not enable any substantial negative pressure differential to “leak” into the enclosed space defined by element 24 and the surface of the eye as shown in Figure 5 therein, for example. It is also noted that the device of Hellencamp is specifically stated to provide a uniform suction force (see column 4, lines 23-28), which is one of the touted advantages of the instant device. Thus this argument is not convincing.

In further argument applicant states that the examiner “noted the importance of precise positioning of the corneal flap, but this misses the point.” On the contrary, the examiner must assert that this is precisely the point. Since the fixation ring is the base upon which the microkeratome rests, (see UP Patent 5,133,726, to Ruiz et al., incorporated by reference in US Patent 5,591,174 to Clark et al, currently applied to the claims, and provided as evidence to support the examiner’s assertions) any imprecision in the placement of the ring must necessarily result in a similar displacement of the microkeratome and thus a displacement of the flap.

Further applicant asserts that the instant device holds the conjunctiva flat. The examiner first notes that there is no disclosure relating to this in the originally files disclosure, and further, it is not clear why the sclera will now suddenly not be drawn into the criss-cross passages of applicant’s device, while being drawn into, e.g. the circular openings of Hellencamp. As

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discussed above, the device of Hellencamp is taught as providing uniform suction. By extension, since this uniformity is due to the plurality of suction ports disposed about the extent of the suction enhancement device (see Hellencamp, column 8, lines 36-53), the L'Esperance (EP '127) device, which discusses no variation in the permeability of wall 11, must provide similar uniformity of suction. As this uniformity is responsible for various advantages provided by the instant device (see the instant response, page 16, first paragraph thereon), these advantages must also be possessed by the two prior art devices.

With regard to the rejection including the Curtin reference, the claims to which it is applied merely require the presence of an adjusting arm. Thus, in view of the arm being used to adjust the position of the apparatus (in contradistinction to applicant's postulated positioning method of the apparatus, as discussed in the instant response at page 18, first full paragraph), which is discussed at column 5, lines 43 to 68 of Curtin, it is not clear how applicant can properly assert that this aspect is not fairly contained within the four corners of the Curtin reference.

With regard to the rejections including the Clark reference, the need to precisely adjust the position of the microkeratome will not vanish when the device is used for surgery, it will still need to be very precisely placed on the cornea, as set forth above. Thus clearly, the positioners of Clark read on the claimed structures/steps and Clark it analogous art. It is further noted that Clark specifically discloses "a microkeratome **11** with infinite adjustment capabilities" (see column 5, lines 11-12, bold type in original). Thus this argument is not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp. Both L'Esperance (EP '127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages. It would have been obvious to the artisan or ordinary skill to employ criss-cross channels in the devices and methods of L'Esperance (EP '127) or Hellenkamp, since this is another configuration that would serve to distribute the vacuum force and thus provides no unexpected result, and to discontinue the vacuum and reposition the apparatus if it is not centered on the cornea, since proper positioning of the corneal flap is critical for refractive surgery, official notice of which is hereby taken, thus producing a device and method such as claimed.

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Curtin. Curtin teaches the use of adjustment arms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ adjustment arms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to adjustably position the device, which is necessary due to the fact that eyes of different individuals will be in different relative locations, thus producing a device and method such as claimed.

Claims 3/1, 4/3/1, 5/3/1, 6/4/3/1, 7/4/3/1, 8/7/4/3/1, 9/7/4/3/1, 10/8/7/4/3/1, and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Clark et al. Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ the X- and Y-axis adjustment mechanisms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can

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be used to position the device, or alternatively to employ the modified tissue/vacuum interface of L'Esperance (EP '127) or Hellenkamp in the device of Clark et al, since Clark et al provide no details of this aspect of the device, and in either case to provide docking screws, since these allow the fixation of devices in the adjustment mechanisms, thus producing a device and method such as claimed.

Claims 3/2, 4/3/2, 5/3/2, 6/4/3/2, 7/4/3/2, 8/7/4/3/2, 9/7/4/3/2, and 10/8/7/4/3/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp and Curtin as applied to claims 2 and 13 above, and further in combination with Clark et al. Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ the X- and Y-axis adjustment mechanisms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to position the device, or alternatively to employ the modified tissue/vacuum interface of L'Esperance (EP '127) or Hellenkamp in the device of Clark et al, since Clark et al provide no details of this aspect of the device, thus producing a device and method such as claimed.

Applicant's arguments filed January 10, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

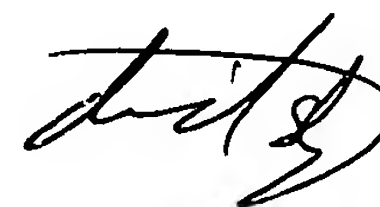
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
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